REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-154 are pending in this case, claims 34-148 having been previously withdrawn under a restriction requirement as drawn to a non-elected invention, and claims 149-154 having previously been added. Claims 1-33, 149, 150, and 152-154 have been rejected. Claim 151 has been objected to.

By this amendment, claims 1, 7-12 and 15-16 have been amended. Claim 155 has been added.

Attached hereinabove is a marked up version of the changes made to the claims by the current amendment.

Claim Rejections – 35 USC § 102 - Holupka

The examiner has rejected claims 1-23, 27, 28, 33, 149-150, and 152 under 35 U.S.C. § 102(e) as being anticipated by Holupka et al. in U.S. Pat. 6,256,529. The Examine's rejections are respectfully traversed. Claims 1, 7-12 and 15-16 have been amended.

In light of the Examiner's opinion that Applicant's arguments filed on January 20, 2004 were not persuasive, claims 1, 7-12 and 15-16 have been amended so as to more clearly distinguish between the claimed invention and the prior art taught by Holupka.

As the Examiner points out in his communication, the amended claims presented by the Applicant in his submission of January 20, 2004 contained inserted language specifying that the loci for insertion of the cryoprobes are <u>operator-specified.</u> The Examiner has responded that Holupka's invention provides an indirect method by means of which a user might in a sense be considered to have indirectly specified positions for insertions of cryoprobes: Holupka's system takes, as input, acquired images representing body organs and other recognizable physiological landmarks, and then generates, based on this input, "pre-determined 'optimal' placement of probes." Holupka's system also provides for user input to define or emphasize contours of organs which may be ambiguously represented in the acquired images. Consequently, user modification or redefinition of the contours of body parts

represented in the images would indeed affect the "pre-determined optimal placement of probes" subsequently determined by Holupka's system.

The amended claims presented above have been modified so as to distinguish the claimed invention from Holupka's teachings. A brief review of the basic structural and functional differences between Holupka's system and that of the instant application may provide a useful context for consideration of the claim amendments in detail.

The planning system of the instant application can be utilized as a training device, in that it is operable to provide feedback to a user regarding the probable results of an intervention specified by that user under a known set of starting conditions. The starting conditions are represented by a three-dimensional model of a portion of a patient's body, which model is based on acquired images, potentially modified by operator input. Thus, in a first act of data input to the system, an operator (optionally) enhances the known structural information about the existing structures of the body, by identifying tissues on the acquired (e.g. ultrasound) images or on a three-dimensional model derived from the acquired images. This first input procedure is common both to Holupka's system and to the system of the instant application.

Once the body structures to be operated on have been so determined, the system of the instant application waits for an operator to present his choices for intervention. In a second act of data input, the operator may specify both his choice of loci into which cryoprobes are to be inserted, and his choice of operating parameters governing the use of those probes during an operation.

In radical contrast to the method described in the paragraph above, the system taught by Holupka does not allow for user input subsequent to the first act of data input wherein the operator optionally contributes to a description of the body structures by defining or re-defining body contours. Once the body structures have been determined (whether by automatic interpretation of the acquired images, or by user-assisted interpretation of those images such as user specification of organ contours based on user interpretation of the acquired images), the determination of the "pre-determined optimal" placement and operating parameters of treatment probes is automatically generated by Holupka's system. Thus there is no possibility that Holupka's system could provide feedback to a user on the probable results of his

user-determined intervention (choice of sites and orientations, number of probes, probe operating parameters) in the context of a defined set of starting conditions.

In summary, both Holupka's system and the system of the instant application provide a possiblity for user intervention in the process of defining what are to be taken as the existing body structures. Yet, once the body-structure model has been determined, the Holupka system automatically selects an "optimal" set of intervention sites and probe operating peramaters, whereas according to the instant application intervention sites and probe operating parameters are user selected, by an act of user intervention which is separate, both in timing and in character, from the act by which the users (of both systems) are optionally enabled to contribute to the system's initial determination of what body structures are to be treated, and where they are.

Consequently, the system of the instant application can be utilized in various ways as a teaching tool and to provide feedback of various kinds to an operator, can make predictions about the results of the operator's choices (choices made subsequent to machine determination and/or user-specification of the structures to be treated), can predict the results of the user's choices, can evaluate those choices in the light of the user's stated goals, and can recommend preferences among user-specified alternative treatments. No such feedback is (nor could be) presented by Holupka's system, since no such user definition of a specified therapeutic act, as a response to the defined set of starting conditions, exists in Holupka's system.

In real life, automatic determination of the desired therapeutic act in the light of a given set of starting conditions may or may not be superior to selection of intervention sites and probe parameters by a surgeon, but in any case the two techniques are certainly quite different.

Holupka does not describe a planning system having an interface useable by an operator for directly specifying loci for insertion of cryoprobes. Holupka does not include a predictor for predicting effects of a user-specified positioning of cryoprobes under a pre-defined set of starting conditions. He does not provide facilities enabling a user to visualize a predicted result of his simulated surgical intervention, nor does he simulate an intervention: careful reading of Holupka's teachings shows that whereas the body structures are presented in a graphic virtual-reality presentation, the *probes* presented in a common virtual space are real-time images of actual inserted probes, and are not simulated inserted probes.

Further, Holupka does not provide an evaluator operable to evaluate a user-specified intervention in terms of user-specified intervention goals. He does not provide means for displaying predicted short-term and long-term results of a simulated intervention, and does not provide means for recommending a choice among a plurality of user-specified simulated interventions, all of which above-listed facilities are provided by the instant disclosure and described by original or amended claims of the instant application.

The Examiner has rejected independent claim 1, stating that "Holupka discloses a planning system for planning a cryosurgical ablation procedure (col 10:28-33), comprising....a simulator (13, col 4:35-40) for simulating a cryosurgical intervention, which comprises an interface useable by an operator for specifying loci for insertion of cryoprobes (19, patented claim 4) and operational parameters (col. 7:56-63) for operation of cryoprobes for cryoablating tissues...."

In the opinion of the Applicant, as expressed in our previous submission, Holupka does not in fact present a system having an interface useable by an operator for specifying loci for insertion of cryoprobes, nor does the system he describes provide for user specification of operational parameters for operation of cryoprobes (nor, equivalently, for the operation of seed-placing catheters). However, in order to more clearly distinguish between the claims of the present application and the cited prior art, claim 1 has been modified, and now refers to two distinguishable acts of operator intervention, a first input act (defining or specifying body structures of the three-dimensional model) which is common both to Holupka and to the instant application, and a second input act (specifying intervention sites and operational parameters) which is unique to the instant application.

Claim 1 now reads:

1. (Currently Amended) A planning system for planning a cryosurgical ablation procedure, comprising:

(a) a first imaging modality for creating digitized preparatory images of an intervention site;

(b) a three-dimensional modeler for creating a three-dimensional model of said intervention site, said three-dimensional model being based on said digitized

preparatory images and optionally being further based on first operator input identifying selected tissues within said three-dimensional model; and

(c) a simulator for simulating a cryosurgical intervention, which simulator comprises:

(i) an interface useable by an operator for inputting second operator input ~~for~~ specifying operator-specified loci for insertion of simulated cryoprobes into a space defined by said three-dimensional model, said interface being further useable by said operator for specifying operator-specified ~~and~~ operational parameters for operation of said simulated cryoprobes for cryoablating tissues; and

(ii) a displayer for displaying in a common virtual space an integrated image comprising a display of said three-dimensional model of said intervention site and a virtual display of said simulated cryoprobes inserted at said operator-specified loci.

It is to be noted that the second input act specified in the claim above is of "loci for insertion of simulated cryoprobes into a space defined by said three-dimensional model", which three-dimensional model is optionally influencable by a prior first input act identifying selected tissues within said three-dimensional model. Thus the two input acts are necessarily distinct.

Description of the first input act is to be found in the instant disclosure on page 48, lines 9-22:

> Interface 264 comprises a highlighter 280 for highlighting, under control of an operator, selected regions within three dimensional model 258. Operator-highlighted selected regions of model 258 are then optionally displayed as part of an integrated image 268.
>
> In particular, highlighter 280 is useable by an operator for identifying tissues to be cryoablated. Preferably, interface 264 permits an operator to highlight selected regions of three dimensional model 258 so as to specify therein tissues to be cryoablated, or alternatively interface 264 permits an operator to highlight selected regions of digitized preparatory images 254, specifying therein tissues to be cryoablated. In the latter case,

three-dimensional modeler 256 is then useable to translate regions highlighted on digitized preparatory images 254 into equivalent regions of three dimensional model 258.

Description of the second input act is to be found in the instant disclosure on pages 47, line 20, to page 48 line 5:

> Three dimensional model 258 is useable by a simulator 260 for simulating a cryosurgical intervention. Simulator 260 comprises a displayer 262 for displaying views of model 258, and an an interface 264 useable by an operator for specifying loci for insertion of simulated cryoprobes 266 and operational parameters for operation of simulated cryoprobes 266 for cryoablating tissues. Thus, an operator (i.e., a user) can use simulator 260 to simulate a cryoablation intervention, by using interface 264 to command particular views of model 258, and by specifying both where to insert simulated cryoprobes 266 into an organ imaged by model 258, and how to operate cryoprobes 266. Typically, an operator may specify positions for a plurality of simulated cryoprobes 266, and further specify operating temperatures and durations of cooling for cryoprobes 266. Display 262 is then useable for displaying in a common virtual space an integrated image 268 comprising a display of three dimensional model 258 and a virtual display of simulated cryoprobes 266 inserted at said operator-specified loci

With respect to the nature of the interface described by Holupka, the attention of the Examiner is first drawn to two passages in which Holupka discusses the positioning of radioactive seeds during an intervention. The first passage, from Holupka's description of prior art, col. 2, lines 36-46:

> Once the 3D contour data has been obtained for the prostate volume, a radiation therapy plan which describes the positions of the radioactive seeds within the prostate is developed. This plan

> attempts to optimize the dose to the prostate, minimize the dose to surrounding healthy tissue, and minimize dose inhomogeneity. The positions of the radioactive seeds are constrained to fall within the catheter tracks, since the seeds are placed within the prostate transperineally via these catheters. The result of the pre-plan describes the positions and strengths of the radioactive seeds within the catheter which optimizes the dose to the prostate.

Applicant believes it is clear from the context that it is Holupka's system, and not the user of that system, that is doing the developing and optimizing mentioned in the paragraph above. That impression is further reinforced by the following passage, from Holupka col. 7 lines 22-34:

> As described above, in the routine process of brachy-therapy planning, the patient undergoes an initial volumetric ultrasound scan using the probe 12. This scan is done before the radiation therapy planning, the ideal positions of the radioactive seeds 18 (see FIG. 1) within the prostate are determined. This ideal seed distribution is optimized to deliver a dose distribution within the prostate that will deliver all the radiation dose to the target volume only, while sparing the surrounding healthy tissue sach as the rectum and bladder. The optimal positions of the seeds 18 and the optimal position of the needles 19 are recorded for later use in the operating room when the needles 19 are loaded into the patient.

Holupka goes on to describe, in lines 38-55, a procedure by which the optimized dosage and position of the radioactive seeds is determined.

As pointed out in the Applicant's previous communication, if the catheter tracks are described as constrained by the positions of the holes in the plastic implant template, and the dosage and position of the radioactive seeds is determined by the software described in column 7, lines 38-55, then there is in fact nothing in Holupka's disclosure that states or implies that the user of his system has a free choice in

describing where his cryoprobes (or seed catheters) are to be placed, nor that the operator has an option of himself specifying dosages.

Thus, Applicant respectfully submits that claim 1 as amended is novel and non-obvious over the disclosures of Holupka, and that therefor claim 1 and the claims dependent thereon are allowable.

Claims 7-12 and 15-16 have been amended so as to be consistent with amended claim 1, and to enhance clarity.

With respect to claims 11-15, 149-150 and 152, it is to be noted that whereas Holupka's system does involve predicting probe effects on tissue, those probe effects are not the result of a user-specified intervention, over and above the user's description of existing body structures, therefore these claims should be considered patentably distinct. Similarly, with respect to claims 4, 16-22 and 153-154, manipulation of images by the operator takes place in the first data input phase, yet the recommendation specified in the instant claims is stated to be relevant to the operator input offered in a second data input phase, which is specifically absent in Holupka's system.

Similarly, with respect to claims 4, 16-22 and 153-154, having to do with Holupka's system as a recommender, it is to be noted that amended claim 1 now specifically refers to recommendations regarding user-specified (simulated) therapeutic acts, as distinguised from user-provided input about existing body structures, therefor the existense of a recommender function in Holupka's system should not provide a barrier to patentability of the instant claims. The same is true of claims 2 (use of a memory), 3 (use of CT, MRI, and US imaging), 4 (use of a Cartesian coordinate system), claims 5-10 (ability to highlight regions), and 23, 27, 28, and 33 (cryosurgical prostate ablation.)

Claim Rejections – 35 USC § 103(a)

The Examiner has rejected claims 24, 25, and 29-30 under 35 U.S.C. 103(a) as being unpatentable over Holupka in view of Mikus et al. ('690).

The Examiner has further rejected claim 26 under 35 U.S.C. 103(a) as being unpatentable over Holupka in view of Mikus et al. ('690) and further in view of Crockett ('488).

The Examiner has further rejected claims 31 and 32 under 35 U.S.C. 103(a) as being unpatentable over Holupka in view of Mikus et al. ('690) and further in view of Fenn et al. ('426).

The Applicant believes that the amendments presented above to claims 1, 7-12 and 15-16, and discussed in detail above in response to the Examiner's 35 U.S.C. § 102(e) rejections, have rendered claim 1 and all claims dependent thereon patentable distinct from Holupka's invention, and therefor to be patentable over Holupka and all combinations of Holupka with Mikus, Crockett, and Fenn.

Allowable Subject Matter

With respect to claim 151, objected to as being dependent upon a rejected base claim, the Applicant believes that the arguments presented above apply similarly to claim 151, which therefor should be found allowable. Nonetheless, claim 151 has also been recast as new claim 155, combining the limitations of claims 1 (as previously amended), claim 11 (as currently amended), and claim 151 (previoiusly added), in conformity with the Examiner's comments on allowable subject matter.

In view of the above amendments and remarks it is respectfully submitted that claims 1-33 and 149-155 are now in condition for allowance. Prompt Notice of Allowance is respectfully and earnestly solicited.

Respectfully submitted,

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Encl.:
Petition for three-month extension fee